

**Notice of Allowability**

Application No.

10/733,582

Applicant(s)

RENNER ET AL.

Examiner

Stuart W. Snyder

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to TD and arguments of 11/21/2006.
2. ☒ The allowed claim(s) is/are 50-56, 58-69, 73-78 and 81-99.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

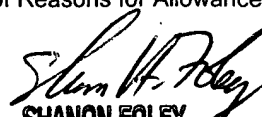
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
**SHANON FOLEY**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 50-56, 58-68, 73-78 and 81-99 are subject of examination. Applicant's election of claims of Group I, species A in the reply filed on 11/21/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Rejection of claims 50-69, 75-78, and 81-97 under 35 USC § 112, 2<sup>nd</sup> ¶ is withdrawn, in view of amended claims.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Rejection of claims 50-53, 69 and 73-78 under 35 USC § 102(b) is withdrawn because of Applicants' arguments are found convincing.

### ***Double Patenting***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Rejection of claims 50-56, 58-69, 73-78 and 81-97 as being unpatentable under the judicially created doctrine of obviousness-type double patenting over various

claims of US Patent No. 6,964,769, US Appl. No.s 10/563,994 and 10/550,518 is withdrawn in view of Applicants' filing of Terminal Disclaimers under 37 CFR § 1.32(c) filed 12/20/2006.

### EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian J. Del Buono on February 1, 2007.

The claims are amended as follows:

66. The composition of Claim 51, wherein said core particle is comprises proteins selected from the group consisting of:
- (a) recombinant proteins of Rotavirus;
  - (b) recombinant proteins of Norwalk virus;
  - (c) recombinant proteins of Alphavirus;
  - (d) recombinant proteins of Foot and Mouth Disease virus;
  - (e) recombinant proteins of Retrovirus;
  - (f) recombinant proteins of Hepatitis B virus;
  - (g) recombinant proteins of Tobacco mosaic virus;
  - (h) recombinant proteins of Flock House Virus; and
  - (i) recombinant proteins of human Papillomavirus.

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73. The composition of Claim 50, wherein said antigen is:
- (a) a recombinant ~~protein of bee sting allergen~~y;
  - (b) a recombinant ~~protein of nut allergen~~y; or
  - (c) a recombinant ~~protein of food allergen~~ies; or
  - ~~(d) a recombinant protein of asthma.~~
81. A method of treatment ~~or prevention~~ of allergies comprising administering to a subject the composition of Claim 50.
83. A method of immunization for the treatment ~~or prevention~~ of allergies comprising administering to a subject a composition comprising:
- (a) a non-naturally occurring molecular scaffold comprising:
    - (i) a core particle selected from the group consisting of:
      - (1) a core particle of non-natural origin; and
      - (2) a core particle of natural origin; and
    - (ii) an organizer comprising at least one first attachment site; wherein at least one said organizer is connected to said core particle by at least one covalent bond; and
  - (b) an antigen or antigenic determinant with at least one second attachment site, said second attachment site being selected from the group consisting of:
    - (i) an attachment site not naturally occurring with said antigen or antigenic determinant; and

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(ii) an attachment site naturally occurring with said antigen or antigenic determinant;

wherein said second attachment site is capable of association through at least one non-peptide bond to said first attachment site;

wherein said antigen or antigenic determinant and said scaffold interact through said association to form an ordered and repetitive antigen array;

wherein said antigen is an allergenic protein; and

wherein said method is suitable for the treatment or prevention of allergies.

89. An vaccine immunogenic composition for the prevention or treatment of allergies comprising:

(a) a non-naturally occurring molecular scaffold comprising:

(i) a core particle selected from the group consisting of:

(1) a core particle of non-natural origin; and

(2) a core particle of natural origin; and

(ii) an organizer comprising at least one first attachment site,

wherein at least one said organizer is connected to said core particle by at least one covalent bond; and

(b) an antigen or antigenic determinant with at least one second attachment site, said second attachment site being selected from the group consisting of:

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(i) an attachment site not naturally occurring with said antigen or antigenic determinant; and

(ii) an attachment site naturally occurring with said antigen or antigenic determinant,

wherein said second attachment site is capable of association

through at least one non-peptide bond to said first attachment site;

wherein said antigen or antigenic determinant and said scaffold interact through said association to form an ordered and repetitive antigen array;

wherein said antigen is an allergenic protein;

wherein said ~~vaccine~~ immunogenic composition is suitable for the treatment ~~or prevention~~ of allergies.

90. The ~~vaccine~~ immunogenic composition of Claim 89 further comprising an adjuvant.

91. The ~~vaccine~~ immunogenic composition of Claim 89, wherein

(a) said core particle is selected from the group consisting of:

(i) a virus

(ii) a virus-like particle;

(iii) a bacteriophage;

(iv) a viral capsid particle; and

(v) a recombinant form of (i), (ii), (iii) or (iv); and

(b) said organizer is a polypeptide or residue thereof; and

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(c) said second attachment site is a polypeptide or residue thereof.

92. The ~~vaccine~~ immunogenic composition of Claim 91, wherein said first and/or said second attachment sites comprise:

- (a) an antigen;
- (b) an antibody or antibody fragment;
- (c) biotin;
- (d) avidin;
- (e) streptavidin;
- (f) a receptor;
- (g) a receptor ligand;
- (h) a ligand;
- (i) a ligand-binding protein;
- (j) an interacting leucine zipper polypeptides;
- (k) an amino group;
- (l) a chemical group reactive with an amino group;
- (m) a carboxyl group;
- (n) a chemical group reactive with a carboxyl group;
- (o) a sulfhydryl group and a chemical;
- (p) a chemical group reactive with a sulfhydryl group; or
- (q) a combination thereof.

93. The ~~vaccine~~ immunogenic composition of Claim 89, wherein said core particle comprises a virus-like particle.

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94. The ~~vaccine~~ immunogenic composition of Claim 93, wherein said core particle comprises a Hepatitis B virus-like particle.
95. The ~~vaccine~~ immunogenic composition of Claim 93, wherein said core particle comprises a measles virus-like particle.
96. The ~~vaccine~~ immunogenic composition of Claim 92, wherein said core particle comprises a virus.
97. The ~~vaccine~~ immunogenic composition of Claim 96, wherein said core particle comprises the Sindbis virus.

***Allowable Subject Matter***

6. Claims 50-56, 58-69, 73-78 and 81-99, as amended, are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The claims are free of the prior art and/or are covered under the aforementioned Terminal Disclaimers.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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